UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC., Plaintiff, v. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	Case No. **JURY TRIAL DEMANDED**

COMPLAINT

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For its Complaint, plaintiff Pfizer Inc. ("Pfizer") alleges against defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, "J&J"), as follows:

PRELIMINARY STATEMENT

1. It is accepted national policy to promote price competition among pharmaceutical manufacturers after an originator firm's patent protection has expired. This policy extends to biologics, a unique category of medications that are derived from living organisms. As one lawmaker put it when adopting applicable legislation, such competition "is good for patient safety, consumer choice . . . and the healthcare system at large." This case is about J&J's efforts to suppress that competition and deprive society of those benefits by, among other things, imposing a web of exclusionary contracts on both health insurers and healthcare providers (e.g., hospitals and clinics) to maintain its stranglehold in respect of an important biologic, brand named Remicade, also known by its generic name, infliximab.

2. For many patients suffering from chronic diseases such as rheumatoid arthritis, plaque psoriasis, and Crohn's disease, the best—and sometimes the only—option for treatment is infusion therapy with infliximab. As these conditions are chronic in nature, patients often require long-term treatment and multiple infusions per year.

3. J&J owned patents protecting infliximab and has been amply rewarded for its invention: Between 1998 and 2016, Remicade was the only infliximab product on the market. This position allowed Remicade to become J&J's best-selling drug by far, generating about $4.8 billion in U.S. sales in 2016 alone. In fact, Remicade is among the best selling drugs in the world. For most uses, at list price Remicade sells for about $4,000 per infused dose and about $26,000 for a full year of treatment. When Pfizer introduced its competing biologic Inflectra (infliximab-dyyb) in 2016, J&J deployed improper exclusionary tactics to maintain the dominance of its flagship product.

4. Inflectra received marketing approval under the Biologics Price Competition and Innovation Act ("BPCIA"). Congress recognized the growing importance of biologics, as well as the growing costs associated with them, and passed the BPCIA in 2010. The purpose of the BPCIA, as its name suggests, is to foster meaningful price competition for long-entrenched branded biologic products—with the ultimate goal of lowering healthcare costs. To facilitate price competition, the BPCIA provides an abbreviated FDA approval pathway for "biosimilar" versions of branded biologic drugs. Biosimilars are products that the FDA has determined to have "no clinically meaningful differences" from the already approved biologic (sometimes referred to as the "reference listed drug" or "RLD") in terms of safety, purity, and potency. Although the BPCIA was enacted in 2010, FDA procedures for implementing the Act did not become effective until a few years later, and biosimilars are only recently beginning to come onto the market, with the first biosimilar approval in 2015.

5. On April 5, 2016, Inflectra received FDA approval as the first biosimilar to Remicade. Pfizer began shipping Inflectra in November 2016 and set its initial list price, often referred to as the wholesale acquisition cost (or "WAC"), at 15 percent below the then-current WAC of Remicade.[1]

6. The threat from Inflectra did not go unnoticed by J&J. Within weeks of Inflectra's launch, J&J began to deploy what it publicly has termed its "Biosimilar Readiness Plan." The core features of the plan are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing.

[1] WAC is the manufacturer's published list price to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price.

7. J&J's actions with respect to Remicade exclude competition at multiple levels:

8. ***Exclusive contracts with insurance company payers.*** Insurer decisions regarding reimbursement policies have a dramatic impact on which infliximab product will be stocked by healthcare providers such as hospitals and clinics. Because providers administer infliximab on site (it is an infusion product), they must use their own funds to stock the product, purchasing it for later use and relying upon subsequent reimbursement from insurers to recoup their expenses. Given the cost of biologic drugs generally, and Remicade in particular, there is almost no chance that providers will pay for a product that is not widely covered by insurers for fear of stocking a product that will not be reimbursed after the provider administers it to a patient, as even a single unreimbursed dose may cost the provider in excess of $4,000.

- Recognizing this, J&J has induced insurers to enter into contracts that require an explicit commitment not to cover Inflectra at all or to do so only in the rarest of circumstances—in effect, to make Remicade the only covered infliximab. As a direct result of these exclusive dealing contractual commitments, Inflectra is either not listed on the insurance company's medical policy—a published listing of the drugs approved for reimbursement under the insurer's medical benefit—or is designated reimbursable only in so-called "fail first" cases. The "fail first" exception, which requires that Remicade has been tried by and failed with respect to a given patient before a biosimilar infliximab can be reimbursed, is medically inappropriate and illusory in practice. If Remicade, which is an infliximab product, does not work for a patient, a physician would turn to a non-infliximab drug, not to Inflectra, which also is an infliximab product and has no clinically meaningful differences from Remicade. The spurious nature of J&J's "fail first" restriction is illustrated by the fact that in early 2017, before J&J's contracts

took hold, the major insurers listed Inflectra at parity with Remicade—indicating that they saw no medical reason to favor one over the other.

- J&J's "fail first" contractual restrictions therefore have the same practical effect as pure exclusive contracts: both operate to exclude Inflectra from qualifying for reimbursement under the insurers' plans; both prevent the insurer from freely reimbursing for Inflectra or another biosimilar without breaching the contracts; and both foreclose Inflectra from competing for patients covered by those plans. J&J has entered into such contracts with all or nearly all national health insurance companies. These "biosimilar-exclusion" contracts, on their own, have foreclosed Inflectra's ability to vie for at least *70 percent* of commercially insured patients in the United States, including a significant number of commercially insured patients who reside in the Philadelphia area. But the foreclosure effects of those insurer contracts go well beyond the immediate impact on patients covered by the affected plans, as discussed below.

9. ***Exclusionary rebates and bundling arrangements with insurance company payers.*** A key to J&J's ability to coerce insurers into accepting its exclusionary commitments is its denial of rebates to insurers that decline J&J's exclusivity commitments, thereby imposing a substantial financial penalty. In effect, J&J says to insurers, "If you want to receive attractive rebates on Remicade for all your existing Remicade patients"—rebates which, for some insurers, run into the tens of millions of dollars annually—"you must agree to not reimburse for Inflectra, or to do so in the most limited of circumstances." In short, insurers that decline J&J's offer face a substantial financial penalty, and those that accept receive a payoff (multimillion dollar rebate payments) in return for their commitment to exclude biosimilars.

- J&J's threatened financial penalty is effective because there is a substantial base of patients across the country who are already controlling their diseases with Remicade and thus

are unlikely to switch to a lower-priced biosimilar once available. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the biologic originator, they are not substitutable without the prescriber's approval (unlike generics for non-biologic drugs approved under the Hatch-Waxman structure, which are substitutable without a new prescription). And, although the FDA's approval permits physicians to switch from the originator to the biosimilar, and Pfizer believes they should consider doing so in appropriate circumstances, as a practical matter, existing-patient Remicade demand is economically incontestable, that is, not a realistic candidate for biosimilar firms to compete for. As the head of J&J's pharmaceuticals business told investors, "the 70% of patients who are [already] stable on Remicade are highly unlikely to switch."[2] J&J bundles this economically "incontestable" demand for Remicade with the portion of demand that is "contestable" for biosimilar firms—new patients starting therapy with infliximab—by threatening to deny rebates on *all* Remicade prescriptions if *any* infliximab biosimilar prescriptions are reimbursed, effectively meaning insurers would have to forfeit their rebates and pay J&J's ever increasing price for the incontestable patients.

- J&J also bundles rebates on multiple *different* products, such that insurers that refuse to grant exclusivity to Remicade would be forced to pay higher prices and/or forego enhanced portfolio rebates. The net effect of these anticompetitive bundling practices is that the insurers subject to them have no real choice but to agree to J&J's exclusivity conditions. Insurers have made it clear to Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. Pfizer and other biosimilar firms cannot feasibly make up the difference for the J&J rebates (on the existing Remicade patient base) that insurers would lose if

[2] Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.

they declined J&J's conditions. Insurers have stated a desire to support biosimilars—and the lower per-unit prices they bring—but realistically cannot do so without incurring a substantial financial penalty imposed by J&J and thus potentially placing themselves at a disadvantage relative to insurers accepting J&J's rebates.

10. ***J&J-engineered coverage restrictions impact provider purchasing behavior and thus magnify foreclosure.*** The foreclosure created by J&J's exclusionary insurer-level contracts goes well beyond the patients covered by these health insurers: Inflectra's coverage status has a spillover effect on the purchasing decisions of healthcare providers (as noted, the clinics, hospitals, and other institutions that purchase and administer infliximab) as well as the prescribing decisions of physicians affiliated therewith. Given the widespread gaps in Inflectra's insurance coverage—engineered by J&J—providers have overwhelmingly chosen to stock *only* Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by insurance plans that *do* cover the product. To take one example, even though Inflectra is covered by Medicare and other government programs, providers have been unwilling to stock Inflectra even for potential use with such government-insured patients. As a result, not only is the federal government forced to continue reimbursing for Remicade, the more expensive product, but the effective foreclosure of biosimilars is expanded well beyond the 70 percent of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about *90 percent* of healthcare provider accounts using infliximab had purchased *no Inflectra at all*. J&J has stoked providers' reluctance to purchase Inflectra by touting with providers the very lack of coverage for Inflectra created by J&J's own exclusionary contracts.

11. ***Exclusionary rebates and bundling arrangements with healthcare providers.*** Beyond the spillover impact described above, J&J has also extended its practices of multi-product bundling and bundling of contestable and incontestable demand in contracts with healthcare providers.

12. J&J's exclusionary plan has been remarkably effective at stifling competition: Today, almost no national commercial health insurer provides coverage for Inflectra (except under the spurious "fail first" scenario), and the vast bulk of healthcare provider accounts using infliximab (approximately 90 percent) have not purchased Inflectra at all. Despite some coverage by regional and government plans, Inflectra has secured *less than 4 percent* of total infliximab unit sales in the U.S. as of September 1, 2017.

13. The harm to Pfizer and to competition as a whole—and, ultimately, to consumers, businesses, and the U.S. government, who bear the brunt of rising healthcare costs nationwide—is manifest. In response to a new entrant offering lower prices for a product deemed to have "no clinically meaningful differences" from the incumbent's brand, basic economics would predict that market-wide prices would fall. Instead, the opposite has occurred. Since the time the FDA approved Inflectra and J&J implemented its publicly-stated plan to block biosimilars like Inflectra, J&J has *raised* the list price of Remicade by close to 9 percent and increased the amount the U.S. government reimburses for Remicade by more than $190 per infused dose. J&J's list price increases are not overcome by increased rebates and discounts: Remicade's "average selling price" ("ASP")—which by federal law is an average of a drug's pricing after taking into account discounts, rebates, and other price concessions—actually has *increased* since Inflectra's entry. As of September 2017, Remicade's ASP was more than 10 percent higher than Inflectra's ASP. Pfizer has offered to guarantee clients that Inflectra would be less expensive

unit-for-unit than Remicade during a contract term. Despite Inflectra's lower per-unit prices, and J&J's escalating prices, Remicade has not lost any substantial volume or share of sales to Inflectra, even though FDA determined there to be no clinically meaningful differences between the two products.

14. In July, J&J extolled the success of its scheme, noting that it had not "seen much of an impact" from Inflectra's entrance, and that J&J is "especially well-prepared to manage through the Remicade biosimilars."[3] J&J also said it was confident that it could fend off even subsequent biosimilar entrants this year because of its exclusionary contracts: "[W]e have our contracting in place with all the managed care organizations [e.g., health insurers]."[4] The net result is that patients (along with healthcare providers and the U.S. government) have fewer choices and pay more than they should.

15. Major stakeholders at every level of the healthcare marketplace are suffering as a result of J&J's competition-reducing actions:

- Most importantly, consumers suffer in the form of artificially inflated prices (including higher coinsurance payments, insurance premiums, and taxes), as well as reduced choice.
- Government programs, including Medicare—and ultimately taxpayers—suffer by having to pay artificially higher prices for the vast majority of their infliximab utilization.
- Pfizer, of course, suffers loss of sales, investment, and reputation as a result of J&J's success in securing commitments to disadvantage Inflectra.

16. Pfizer brings this action under the antitrust laws of the United States to challenge J&J's anticompetitive conduct. If J&J's conduct is allowed to continue, its "Biosimilar

[3] Johnson & Johnson, Q2 2017 Results Earnings Call Transcript (July 18, 2017), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.
[4] *Id.*

Readiness Plan" will become the playbook for biologic originator firms seeking to preserve their dominance in the face of biosimilar competition—thus subverting the competition-enhancing objectives of the BPCIA.

17. Allegations relating to Pfizer's conduct are based on personal knowledge; other allegations are based on Pfizer's research, publicly available sources, feedback from customers, and information and belief.

THE PARTIES

18. Plaintiff Pfizer is a corporation organized and existing under the laws of Delaware. Pfizer's principal place of business in the United States is located at 235 East 42nd Street, New York, New York 10017. Pfizer is a research-based international pharmaceutical company which researches, develops, manufactures, and sells pharmaceutical products across the spectrum, from branded innovator products to generics and over-the-counter medications. Pfizer is also committed to developing biosimilar medications to bring competition, lower prices, and choice to patients.

19. Pfizer has commercialized Inflectra, a biosimilar to J&J's Remicade, through its partnership with Celltrion, the holder of the drug product's Biologics License Application. The FDA approved Inflectra as a biosimilar to Remicade on April 5, 2016.

20. Defendant Johnson & Johnson is a corporation organized and existing under the laws of New Jersey. Johnson & Johnson's principal place of business in the United States is located at One J&J Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is an international pharmaceutical company—one of the largest in the world—and was the sole supplier of infliximab, marketed as Remicade, between 1998 and 2016, when Inflectra came to market.

21. Defendant Janssen Biotech, Inc. ("Janssen") is a wholly owned subsidiary of Johnson & Johnson. Janssen is a corporation organized and existing under the laws of Pennsylvania. Janssen's corporate headquarters are located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

22. This action arises under the antitrust laws of the United States, including Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

23. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1337(a).

24. Johnson & Johnson may be found, transacts business, and is subject to personal jurisdiction in this judicial district.

25. Janssen may be found, transacts business, and is subject to personal jurisdiction in this judicial district.

26. The violations of law alleged in this Complaint took place, in part, in this judicial district and have injured Pfizer in this district. Venue is therefore appropriate in the Eastern District of Pennsylvania under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. §§ 1391(b) and (c).

27. The creation, marketing, sale, and distribution of Remicade and Inflectra, and the actions complained of in this Complaint, occur in and substantially affect interstate commerce.

FACTUAL AND REGULATORY BACKGROUND

A. Biologics

28. Biologics are treatments derived from living systems such as microorganisms or plant or animal cells. As the FDA explains: "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available."[5] In contrast to most drugs, which are chemically synthesized and whose structure is known, most biologics are complex mixtures that are not easily identified or characterized.[6]

B. Congress Enacts the Biologics Price Competition and Innovation Act to Spur Price Competition for Biologic Medications

29. Congress has made clear that competition in pharmaceuticals is to be encouraged, and, to that end, in 1984 enacted the Hatch-Waxman Act ("Hatch-Waxman"), which established an abbreviated pathway for approval of generic counterparts to non-biologic branded drug products. Before Hatch-Waxman, a generic applicant had to conduct the same kinds of safety and efficacy studies (including large clinical trials and the like) as the originating drug manufacturer. Such a process, which can cost hundreds of millions of dollars and take years to

[5] *See* U.S. Food & Drug Administration, *What Are "Biologics" Questions and Answers*, https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm (last visited Sept. 18, 2017).

[6] *Id.*

complete, was prohibitive for would-be generic entrants and led to the near absence of generic competition to branded drug products. Hatch-Waxman eliminated this hurdle; it allowed generic firms to rely upon the originator's safety and efficacy studies. Generic applicants need only show that their products use the same active pharmaceutical ingredient as the originator, and that their products are bioequivalent (e.g., that the generic product's uptake into the body is equivalent to the branded drug). A principal goal of Hatch-Waxman was to trigger price competition with originator products, many of which had enjoyed longstanding exclusivity. That goal has been achieved: According to the FDA, the competition spurred by Hatch-Waxman has saved *more than $1.6 trillion* for patients and the healthcare system.[7]

30. However, for a number of reasons, biologic products generally are not covered by the Hatch-Waxman procedures. Nevertheless, given the success of Hatch-Waxman in spurring competition for non-biologic medicines, Congress and nearly all stakeholders in the healthcare system have recognized the great desirability of having an analogous system for biologics.[8]

31. In 2009, Congress addressed the need for competition in the biologics marketplace by introducing the BPCIA, which was signed into law in 2010. The Act furthers the "FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of . . . testing."[9]

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[7] *See* Kathleen "Cook" Uhl, *2016: A Record-Setting Year for Generic Drugs, U.S. Food & Drug Administration* (Feb. 24, 2017), available at https://blogs.fda.gov/fdavoice/index.php/2017/02/2016-a-record-setting-year-for-generic-drugs/ (noting that "2016 was a record-setting year for FDA's generic drug program," and that "[o]ver the last 10 years, generic drugs have saved the U.S. healthcare system about $1.68 trillion").

[8] *See* U.S. Food & Drug Administration, *Implementation of the Biologics Price Competition and Innovation Act of 2009* (Feb. 12, 2016), available at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm215089.htm ("The goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a. the 'Hatch-Waxman Act') which created abbreviated pathways for the approval of drug products under Federal Food, Drug, and Cosmetic Act (FFD&C Act).").

[9] U.S. Food & Drug Administration, *Implementation of the Biologics Competition and Innovation Act of*

32. A principal purpose of the Act—as reflected in its very name (i.e., the Biologics *Price Competition* and Innovation Act)—was to spur price competition in biologic drug products:

- "We have to find a way to introduce competition into [the biosimilar] market," including balancing "giving incentives for development of new products but bringing about the benefits of competition in the marketplace." (Hon. Henry Waxman, United States Representative from California)
- "Legislation to facilitate the development of biosimilars should promote competition and lower prices[.]" (Hon. Anna G. Eshoo, United States Representative from California)
- "We want to foster a robust biosimilar market." (Hon. Joe Barton, United States Representative from Texas)
- "[C]ompetition [from biosimilars] is good for patient safety, consumer choice, and drive[s] savings for consumers and the healthcare system at large." (Hon. Gene Green, United States Representative from Texas)

33. The BPCIA provides an abbreviated regulatory approval pathway for the introduction of biosimilars. A biosimilar applicant may rely on the clinical studies of the reference listed drug if it can show: (a) that the proposed biosimilar is "highly similar to the [originator product, or RLD] notwithstanding minor differences in clinically inactive components"; and (b) that "there are no clinically meaningful differences between the [proposed biosimilar] and the [RLD] in terms of safety, purity, and potency." 42 U.S.C. § 262(i)(2).

34. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the RLD, they are not automatically substitutable with the RLD (unlike Hatch-Waxman generics). Thus, if a doctor prescribes the RLD, a pharmacist cannot substitute a biosimilar unless that product has been designated as interchangeable by FDA and the relevant

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2009, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm (last visited Sept. 18, 2017).

state law permits substitution of interchangeable biologics.[10] This allows originator firms to retain the bulk of their existing patient bases, which typically is not possible for a branded firm to do when a Hatch-Waxman generic enters (because state substitution laws permit prescriptions for the brand to be automatically substituted with the Hatch-Waxman generic by the pharmacist without the need for physician intervention). This difference enables biologic originator firms to leverage their monopolies over existing patients to extract anticompetitive commitments from insurers and providers.

C. Infliximab

35. Infliximab is a tumor necrosis factor ("TNF")-inhibiting biologic drug used to treat a range of immune-mediated diseases, including Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.

36. As a biologic, infliximab is not synthesized in a laboratory, but rather derived from a living organism. Infliximab is a chimeric IgG1κ monoclonal antibody (composed of human constant and murine variable regions) specific for human tumor necrosis factor-alpha. Infliximab is produced by a recombinant cell line cultured by continuous perfusion and is purified by a series of steps that includes measures to inactivate and remove viruses.

37. Infliximab is an infusion therapy, meaning it is administered intravenously. Thus, infliximab patients must (in most cases) visit clinics, hospitals, or other medical facilities to receive the therapy from healthcare professionals. As a result, patients rarely purchase

[10] The BPCIA does provide for an "interchangeable" designation, but FDA published draft guidelines for establishing interchangeability only this year. U.S. Food & Drug Administration, *Considerations in Demonstrating Interchangeability With a Reference Product (Draft Guidance)* (Jan. 17, 2017). And while Pfizer believes that Inflectra can be safely and effectively substituted for Remicade (indeed, studies have shown that switching patients can be done safely and effectively, and Pfizer has supported and/or taken part in some of these studies), it will be years before Inflectra or any other biologic receives a formal "interchangeability" designation from FDA in the United States. Nonetheless, neither the BPCIA nor FDA contemplates that biosimilars should be prevented from competing in the marketplace—i.e., that consumers should be denied access to them—until they are designated interchangeable.

infliximab themselves at retail pharmacies. Instead, infusion centers, clinics, and hospitals purchase infliximab, and after administration, seek reimbursement from the patient's insurer or a government payer (e.g., Medicare). Infliximab is an important medicine that has provided life-changing benefits to millions of patients.

D. J&J's Remicade

38. J&J introduced the first infliximab product in the United States in 1998, under the brand name Remicade.

39. Remicade is widely used: An estimated 475,000 patients in the U.S. receive at least one dose of Remicade annually. This fact, combined with the cost (approximately $4,000 per infused dose at list price), makes administering Remicade a major expense item for insurers and healthcare providers.

40. J&J's list price increases for Remicade and other pricing actions have resulted in consistent increases in Remicade's ASP. J&J has increased the price of Remicade without experiencing a loss of sales to other therapies. Instead, Remicade sales have increased steadily since it was introduced. Indeed, J&J has been able to continue raising the price of Remicade notwithstanding the arrival of Inflectra.

41. Since 1998, J&J has made billions of dollars in profit on Remicade.

E. Pfizer's Inflectra

42. Beginning in 2008, Celltrion undertook to develop a biosimilar to Remicade and move it through the intensive FDA review process. The Biologics License Application for Inflectra was filed with FDA in 2014. After rigorous scientific review, FDA approved infliximab-dyyb on April 5, 2016. In the FDA news release announcing its approval of Inflectra, the director of FDA's Center for Drug Evaluation and Research reiterated that approval as a biosimilar reflects a determination of "no clinically meaningful differences" from the originator,

and stated that "[p]atients and the health care community can be confident that biosimilar products are high quality and meet the agency's rigorous scientific standards."[11]

43. J&J claimed patent protection over Remicade—as noted, making it the sole provider of infliximab for nearly two decades—and thus Pfizer and Celltrion were forced to defend against J&J's patent suit in parallel with FDA's regulatory review of the Inflectra application. On August 17, 2016, J&J's patent covering the infliximab antibody was ruled invalid by the United States District Court for the District of Massachusetts, a ruling which confirmed that J&J had no valid right to exclude Pfizer (or other potential biosimilar entrants). The Court held that the antibodies covered by J&J's Remicade patent had been disclosed and claimed in an earlier patent.[12] Just a few months after the district court ruling, the U.S. Patent and Trademark Office issued a final decision in a re-examination of the same patent, holding that the patent was invalid.[13]

44. After overcoming these hurdles, and after a 180-day notice period required by the BPCIA, Pfizer began selling Inflectra in November 2016.

45. Inflectra is approved for all the same indications as Remicade, except pediatric ulcerative colitis, as to which J&J continues to enjoy an FDA-granted period of exclusivity because of the indication's status as an "orphan" indication (established on proof that the number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons), which is scheduled to end in 2018. On that date, Inflectra will be eligible to

[11] *See* U.S. Food & Drug Administration, *FDA Approves Inflectra, A Biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

[12] Janelle Lawrence, *J&J Remicade Patent Found Invalid in U.S. Victory for Pfizer*, Bloomberg (Aug. 17, 2016), https://www.bloomberg.com/news/articles/2016-08-17/j-j-patent-on-remicade-expiring-in-2018-invalid-judge-rules.

[13] *Id*.

seek approval for pediatric ulcerative colitis. In any event, this indication accounted for less than 5 percent of overall infliximab utilization in 2016.

46. Pfizer introduced Inflectra with a list price 15 percent lower than Remicade's, and, in negotiations with insurers and providers, offered substantial additional pricing concessions in the form of discounts and/or rebates that in some instances were more than 40 percent below Inflectra's list price. The goal and effect was to offer Inflectra for less than J&J was offering Remicade; indeed, for many customers, Pfizer committed to ensure that Inflectra would have a lower net per-unit price than Remicade.

47. Given that it was charging a lower price for Inflectra than J&J was charging for Remicade, Pfizer was optimistic that it would have an opportunity to compete, to secure a reasonable share of the business, particularly for new patients, and to bring the benefits of price competition to consumers, providers, insurers, and the U.S. government. However, due to J&J's exclusionary conduct, competition has been foreclosed. J&J maintains its monopoly and has continued to capture over 96 percent of infliximab sales even while maintaining prices far above competitive levels.

F. The Importance of Insurance Coverage for Infliximab

48. Most patients who are prescribed Remicade have some form of insurance coverage or qualify for patient assistance. The sources of insurance coverage are (a) private insurance, accounting for about 60 percent of patients nationally, and (b) government insurance programs (principally Medicare and Medicaid), accounting for the remaining 40 percent. Insurance coverage and reimbursement are therefore key to the adoption of the product by patients and healthcare providers alike. If a product as expensive as Remicade is not widely reimbursed, it will not be significantly utilized.

49. Because Remicade is not dispensed in a retail pharmacy but rather administered intravenously in a clinic or other institutional setting, it generally is not included under the "pharmacy benefit" of most health plans. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication him or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and out-of-pocket payment (usually, a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected, i.e., the drug is not purchased and stocked in advance by providers at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

50. In contrast, "medical benefit" products such as Remicade are administered at a clinic or other healthcare provider site, and the provider *itself* first purchases the drug product for use in the infusion treatment of patients, and then later seeks reimbursement for the drug from a third party payer (a practice commonly referred to as "buy and bill"). When a treatment is administered, the provider must secure payment for the service, including the cost of the product dispensed (which the provider had to pay up front with its own funds). In this context, the provider has a strong interest in utilizing drugs that are widely covered by insurance, particularly by the major national commercial health insurers and significant regional insurers active in its area. If a drug product is not widely covered, such that there is a risk that coverage might be denied, and providers thus would be burdened with a potential financial loss for what they paid for the product, providers are much less likely to purchase that product—a response that is in line with the providers' economic interests (to be reimbursed).

51. Many of the facilities administering infusion services of the type at issue here are physician-owned. Thus, the physicians themselves have both prescribing authority and a strong financial incentive to avoid products that are not widely covered.

52. Commercial insurers typically publish medical policies enumerating the drug products they will cover under the medical benefit and the terms under which they will do so. For example, medical policies may exclude drugs from coverage, or they may dictate restrictions on use. Drug manufacturers compete, usually with rebates or other price concessions, to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors—or, at a minimum, to achieve "parity" whereby the competing products have the same restrictions on reimbursement and the patient and/or doctor can choose between them. Securing at least parity placement is critical, especially for new products seeking to gain traction in the marketplace, and particularly with large insurers, which have tens of millions of covered patients.

G. The Importance of Access at the Provider Level

53. As discussed above, providers (hospitals, clinics, etc.) are the market actors that actually purchase infliximab for use with their infusion services for patients. J&J's agreements and conduct have the effect of foreclosing this essential source of distribution.

54. Providers do not want to risk being unable to secure reimbursement for any drug used to treat a patient after having already paid for the product. Because it can be costly to monitor coverage status across myriad insurers and implement procedures to match product use to a patient's coverage, gaps in reimbursement policies give "buy and bill" provider accounts reasons to stock only products with universal (or near-universal) coverage. Here, due to J&J's anticompetitive contracts at the insurer level, J&J has succeeded in preventing biosimilar competitors from achieving the same status.

J&J'S EXCLUSIONARY SCHEME

55. Not content with its nearly two full decades of exclusivity with Remicade, and the billions of dollars of profits that such exclusivity enabled, J&J hatched a multifaceted scheme to ensure that biosimilars would never become viable competitors—a scheme embodied, at least in part, in its "Biosimilar Readiness Plan." J&J revealed the existence of the plan, and at least some specifics thereof, during a recent investor call and presentation.[14] And a J&J consultant bragged at a recent health conference that his firm helped design the plan to realize J&J's goal of ensuring that biosimilars never gain a foothold.

56. J&J's conduct has not gone unnoticed in the industry. For example, an analyst at a prominent securities firm (Bernstein Research) recently summarized key aspects of J&J's scheme, observing that J&J has: (a) "negotiated with [insurers]" and set up "exclusive contracts . . . in nearly half the market," thereby making providers unwilling to purchase Inflectra; (b) "offered up deeper discounts to large independent infusion centers [i.e., major providers], which are more economically sensitive"; and (c) "bundled several drugs and medical devices [together] for larger hospitals."[15] The analyst also noted that a key to J&J's strategy was the "long 'tail' of [patients] remaining on the brand"[16]—the incontestable demand—which gives J&J leverage to extract commitments from insurers not to cover Inflectra.[17] Another industry observer,

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[14] Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.

[15] Aaron Gal, *Biosimilars: So, Why Has Remicade Biosimilar Not Gotten Much Traction in the U.S.*, Bernstein Research, at 1 (July 20, 2017).

[16] *Id.*

[17] While the Bernstein survey suggests that Pfizer has offered only a "'low single digit' discount off of the ASP" of Inflectra, that is not accurate. As set forth herein, Pfizer has offered Inflectra at a significant discount (to list price as well as ASP), but continues to be foreclosed by J&J's anticompetitive contracts. J&J, meanwhile, has raised the price of Remicade since Inflectra's entry. The Bernstein survey also speculates that with the entry of a third biosimilar in mid-2019, "we would likely [sic] see one of the biosimilars crossing the Rubicon and offering the required discounts." Gal, *supra* note 15, at 1. However, as set forth herein, J&J's exclusive contracts and bundling practices foreclose all new biosimilar entrants, including Pfizer, from competing with Remicade on price and, if not stopped, will

commenting on the Bernstein survey, noted that J&J's "fail first" requirements with insurers "force hospitals and clinics to buy Remicade." The observer also noted that:

> J&J has had yet another advantage—an ability and willingness to bundle different medicines as part of a package deal. By offering discounts and rebates for several drugs, J&J can secure contracts and crowd out rivals. And discounts are also appealing to physicians who run their own infusion centers.[18]

57. J&J's scheme is set forth in more detail below:

A. J&J Bars Access to Insurer Reimbursement Through Improper Exclusive Contracts and Anticompetitive Bundling Practices

1. J&J's Exclusive Contracts with Health Insurers

58. A centerpiece of J&J's strategy to block competition from biosimilars has been to secure contractual commitments from commercial insurance companies to exclude biosimilars from coverage under their plans, making Remicade the exclusive infliximab available to patients covered by those plans. Such contractual commitments have taken various forms. Some insurers have entered into contracts with J&J that required them simply to exclude biosimilars from their medical policies and/or drug formularies altogether. Other J&J contracts have imposed a spurious requirement that the biosimilar could be reimbursed only after a patient first tried and failed on Remicade (the "fail first" requirement), which virtually ensures that the biosimilar will never be prescribed and never be reimbursed. If a patient fails on Remicade, it would defy sound medical judgment for a physician to switch to the therapeutically equivalent biosimilar, which works in exactly the same way, rather than another therapy, to which a patient may potentially respond differently.[19] Regardless of their specific form, these contracts all had

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allow J&J to continue to maintain the monopoly power it currently exercises with Remicade.

[18] Ed Silverman, *J&J Now Has Two Competitors for A Pricey Blockbuster. Will That Finally Drive Down Prices?*, Stat News (July 25, 2017), https://www.statnews.com/pharmalot/2017/07/25/merck-samsung-biosimilar-pfizer-johnson/.

[19] The notion that attempting treatment with a biosimilar after its reference listed drug has first failed would defy medical judgment recently has been reinforced in the European League Against Rheumatism rheumatoid arthritis management recommendations. In those recommendations, "[t]he Task Force

the same effect—to exclude biosimilars from coverage and (as one analyst recently confirmed) grant an "exclusive" to Remicade.[20]

59. J&J has induced most major health insurers, covering at least 70 percent of commercially insured patients in the United States, to adopt these improper contractual exclusivity restrictions and to impose outright bans on Inflectra's coverage or so-called "fail first" requirements. These insurers include (in decreasing order of patients covered):

National insurers:

***(a) UnitedHealthcare*:** UnitedHealthcare adopted the "fail first" requirement. UnitedHealthcare has approximately 30.6 million covered commercial medical patients across all 50 states.

***(b) Anthem*:** Anthem excluded Inflectra from coverage altogether. Anthem has approximately 30.4 million covered commercial medical patients concentrated in 14 states.

***(c) Aetna*:** Aetna adopted a complex set of indication specific conditions which operate in practice as "fail first" requirements. Aetna has approximately 17.9 million covered commercial medical patients in all or nearly all states and territories in the United States.

***(d) Cigna*:** Cigna adopted the "fail first" requirement. Cigna has approximately 13 million covered commercial medical patients across all 50 states.

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reiterated its position that if a TNF-inhibitor fails, another TNF-inhibitor—but not a biosimilar of the same molecule!—can be as effective as changing the mode of action." Smolen, J.S., et al., *EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-Modifying Antirheumatic Drugs: 2016 Update*, Annals of the Rheumatic Diseases 2017:0:1-18 (Mar. 6, 2017).

[20] Gal, *supra* note 15, at 1.

Regional insurers:

***(a) HealthNet (Centene)*:** HealthNet adopted a complex set of indication specific conditions which operate in practice as "fail first" requirements. HealthNet (as part of its acquisition by Centene) has approximately 12 million covered commercial medical patients concentrated in 28 states.

***(b) CareFirst/Blue Cross Blue Shield*:** CareFirst adopted the "fail first" requirement. Indeed, CareFirst agreed with J&J that Inflectra would be non-preferred, meaning it cannot be reimbursed unless there are "clinical circumstances that would exclude the use of . . . preferred products," including Remicade. CareFirst has approximately 3.2 million covered commercial medical patients principally found in Maryland, Virginia, and the District of Columbia.

***(c) Blue Cross Blue Shield of North Carolina*:** BCBS of North Carolina adopted the "fail first" requirement. BCBS of North Carolina has approximately 2.7 million covered commercial medical patients concentrated in North Carolina.

***(d) Blue Cross Blue Shield of Tennessee*:** BCBS of Tennessee adopted the "fail first" requirement. BCBS of Tennessee has approximately 1.6 million covered commercial medical patients concentrated in Tennessee.

***(e) Blue Cross Blue Shield of Louisiana*:** BCBS of Louisiana adopted the "fail first" requirement. BCBS of Louisiana has approximately 1.6 million covered commercial medical patients principally concentrated in Louisiana.

***(f) Excellus Blue Cross Blue Shield*:** Excellus BCBS adopted the "fail first" requirement. Excellus has approximately 1.2 million covered commercial medical patients concentrated in New York.

***(g) Independence Blue Cross*:** Independence Blue Cross adopted the "fail first" requirement. Independence Blue Cross is the leading health insurer in Philadelphia.

These contracts alone affect approximately 114 million covered commercial medical patients of the over approximately 214 million patients covered by commercial medical insurance in the United States. Pfizer has reason to believe there are more.

60. While exclusive contracts can—in certain circumstances—be perfectly appropriate, the exclusivity provisions described in Paragraphs 8, 9, and 58 serve no legitimate or procompetitive purpose and were not earned through simple price competition. After Inflectra's FDA approval in April 2016, and before J&J implemented its exclusionary contracts, health insurers undertook reviews to determine whether there was a *medical* reason not to reimburse Inflectra or to disfavor it relative to other therapies. Following these reviews, several major health insurance companies—including at least Aetna, Anthem, and UnitedHealthcare—classified Inflectra at *parity* with Remicade. This confirmed that there was no medical reason justifying a restrictive reimbursement policy toward Inflectra. It also meant that, for the time being, Inflectra would be reimbursed without restriction. As a result, the stage was set for Inflectra to begin competing head-to-head with Remicade on a level playing field—and for patients to begin receiving the benefits of greater choice and lower prices.

61. But this initial state of affairs was short lived. As a result of J&J's anticompetitive conduct, insurers began to reverse course and restrict coverage of Inflectra.

62. For example, in October 2016, UnitedHealthcare, the nation's largest health insurer, with over 30 million covered commercial medical patients, published an update to its medical and site of care policies classifying Inflectra at parity with Remicade for the approved indications (with an effective date of November 1, 2016). This meant that, for UnitedHealthcare,

Inflectra would be reimbursed freely and would not be disfavored relative to Remicade. Just *weeks later*, however, UnitedHealthcare reversed course. UnitedHealthcare classified Remicade as its "preferred" product, and instructed that Inflectra would be eligible for reimbursement only in circumstances so limited as to be practically non-existent. Under UnitedHealthcare's new policy, Inflectra could be reimbursed only where the following conditions are met: (a) the patient must show a minimal clinical response, or an intolerance or adverse reaction, to Remicade; (b) the physician must attest that Inflectra would not lead to the same adverse responses; and (c) the patient must show no loss of favorable response in established maintenance therapy with Remicade, and must not have developed neutralizing antibodies to any infliximab biosimilar product that has made the therapy less effective. As a practical matter, this meant that Inflectra would not be reimbursed for UnitedHealthcare's more than 30 million commercial medical members, and that Remicade would be the exclusive infliximab with UnitedHealthcare—despite the lack of any medical basis for denying those members access to a lower-priced alternative to Remicade.

63. UnitedHealthcare's reversal, of course, did not happen by chance. J&J induced UnitedHealthcare to enter into an exclusive deal by threatening to penalize UnitedHealthcare with the loss of significant rebates unless UnitedHealthcare agreed to deny coverage of Inflectra.

64. J&J has employed the same approach to secure exclusive deals with most or all of the major insurers identified above. In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers—as adopting any alternative would require the insurer to incur a substantial penalty (i.e., foregone rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term.

2. J&J's Bundling Tactics with Health Insurers

65. J&J's threatened penalties are effective because they leverage the large base of existing patients already stabilized on Remicade. Given that J&J has offered the only infliximab option in the United States for nearly two decades, its base of existing Remicade patients is substantial, amounting to hundreds of thousands of patients across the country. And, in part driven by J&J's marketing efforts to secure this outcome, existing Remicade patients are likely to stay on Remicade. Thus, the demand for Remicade associated with this existing base of patients is, as a practical and economic matter, incontestable. This is so despite the fact that switching is within the scope of FDA's approval for use of biosimilars and thus appropriate when medically directed—something Pfizer discusses with clients. The situation is different for *new* patients who may be candidates for infliximab. In light of this, Pfizer has focused, among other things, on competing for a substantial share *of new patient starts* (the "contestable" demand) by pricing Inflectra competitively with both insurers and providers on a unit-for-unit basis. The fact that Inflectra's ASP is lower than Remicade's underscores the cost savings it offers.

66. By threatening to withhold attractive rebates on *all* Remicade prescriptions—including those for existing patients as well as new ones—unless an insurer agrees to exclusivity, J&J is able to leverage the incontestable demand for Remicade to exclude competition for the contestable demand, i.e., it bundles the contestable and incontestable demand. Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar. A recent article by two Yale Medical School professors in the *Journal of the*

American Medical Association illustrates how the kind of leverage J&J has over existing, stable Remicade patients allows it to extract commitments to exclude the biosimilar:

> If a biosimilar manufacturer intends to upend the preferred position of the brand by offering a substantial price discount to the [insurer], the branded manufacturer can respond by withdrawing the rebate on the [branded] biologic, ***creating a "rebate trap."*** For any patient continuing the [branded] biologic, a payer's cost for that patient will double once the rebate is withdrawn . . . . Even in [an] optimistic scenario, in which the price of the biosimilar is 60 percent less than the price of the brand after rebates and discounts, if the payer is only able to convert 50 percent of its patient users to the biosimilar [because existing patients will tend to stay on the original branded product], ***the rebate trap ensures that payer total costs actually increase relative to costs prior to biosimilar availability***.
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> * * *
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> To avoid the rebate trap, any strategy to reduce spending on biologics through adoption of biosimilars requires a near-complete switch of patient users from the branded biologic to the biosimilar. However, for many chronic diseases, the proportion of patients new to a given biological therapy is less than 20 percent of the total patients taking that drug in a given year. The remainder ***represents a stable base of patients whose disease is well-maintained while they are using current therapy and thus are unlikely to switch [to the biosimilar].***[21]

67. J&J has further insulated its contracts with insurers from competition by bundling rebates for Remicade with rebates on other products in return for commitments not to cover Inflectra. J&J made it no secret that it would leverage other products as part of its "Biosimilar Readiness Plan." As J&J's Worldwide Chair for Pharmaceuticals made clear on a recent earnings call, "We are fully prepared to execute our focused biosimilar readiness plan," including "developing innovative contracts . . . [to] utilize the full breadth of our portfolio."[22] The "full breadth of [J&J's] portfolio" includes several drugs for which Pfizer does not offer any directly competing alternative. These include drugs such as Simponi (used for rheumatoid

[21] Aaron Hakim & Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, Journal of the American Medical Association (May 1, 2017), available at http://jamanetwork.com/journals/jama/article-abstract/2625049 (emphasis added).

[22] Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.

arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis), Simponi Aria (used for rheumatoid arthritis), and Stelara (used for plaque psoriasis, psoriatic arthritis, and Crohn's disease). These products are widely used, with Simponi/Simponi Aria generating for J&J approximately $1.7 billion in 2016 and Stelara generating for J&J approximately $3.2 billion in 2016. J&J has threatened insurers with the loss of rebates on these other drugs, as well as Remicade, if they do not agree to exclude Inflectra from coverage.

68. J&J's multi-product bundling, along with its bundling of contestable demand (i.e., new patients) and incontestable demand (i.e., existing Remicade patients), have amplified the anticompetitive effects of J&J's exclusive contracts, and made the exclusivity provided by those contracts even more durable. Insurers have made it clear to Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. But, because of the combined effect of these bundles, Pfizer cannot offset the financial penalties that J&J threatens to impose on insurers who do not agree to exclusivity. As a result, Pfizer is economically prohibited from competing for coverage by the major insurers—even when their exclusive contracts with J&J expire. J&J can use the same bundling strategies to ensure continuation of the exclusionary pattern.

B. J&J's Improper Insurer-Level Contracts Deter Hospitals and Clinics from Purchasing Inflectra, Thus Amplifying Foreclosure

69. Providers are unwilling to stock a drug product where there is significant uncertainty about whether it will be reimbursed by health insurers; because they administer infliximab onsite, providers must expend funds for the product in the first instance, then seek reimbursement after providing treatment. The provider has theoretical recourse against the patient where coverage is denied, but the prospect of securing payment in full from the patient is bleak, especially for drugs as costly as Remicade. As a result, where a significant portion of a

provider's patients are insured by plans that have agreed to exclude Inflectra—pursuant to the types of contracts described above—the provider is unlikely to offer Inflectra for *any* of its patients, to avoid being caught with no reimbursement.

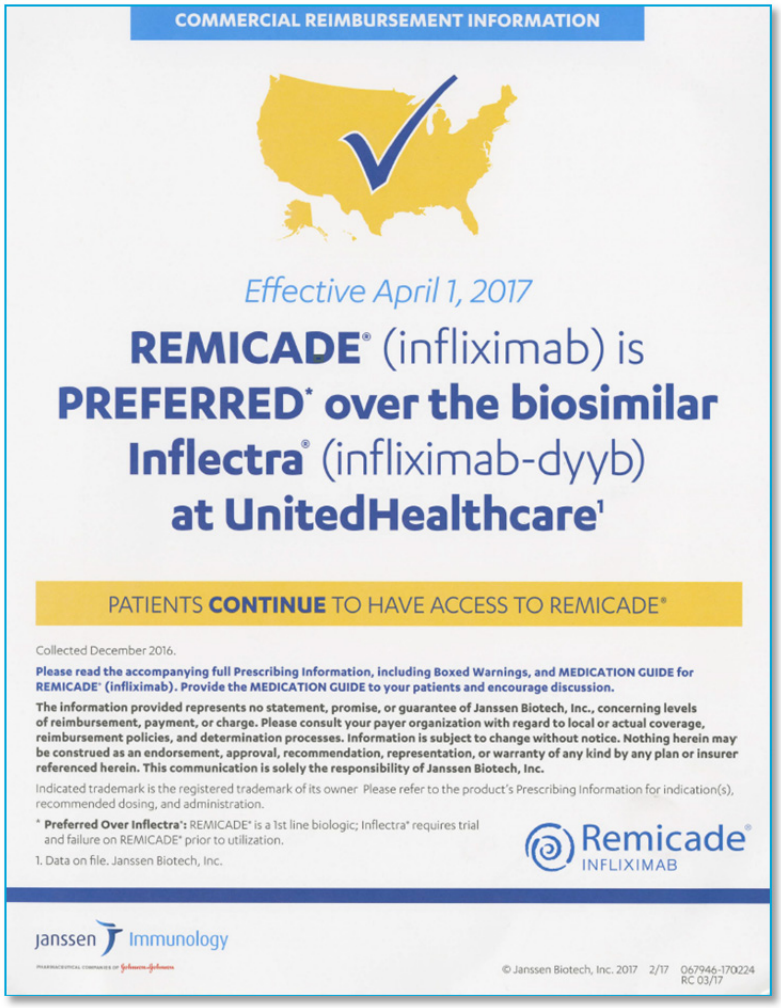
70. As a recent article in *Bloomberg* stated:

> Ascension Health, a nearly 23,000-bed nonprofit hospital system based in St. Louis, spends $55 million a year on Remicade, more than any other drug. Using Inflectra, part of a new class of medicines called biosimilars, would save it at least $10 million annually, according to Ascension's chief pharmacist, Roy Guharoy. He met with Pfizer and planned to integrate Inflectra into care more often until learning that insurers preferred to stay with Remicade. "This we did not expect," Guharoy said. "If the insurance companies force us to use the branded product, of course our hands are tied."[23]

In short, provider purchases are driven by the coverage stated by commercial insurers.

71. Having created reimbursement concerns through its exclusionary contracts with health insurers, J&J touts the excluded status of Inflectra in its marketing communications, knowing that doing so will discourage providers from stocking the new biosimilar. As this brochure shows, J&J markets the "fail first" requirement as a selling point despite the fact that such a provision is medically inappropriate and despite FDA's determination that there are no clinically meaningful differences between the two products. Thus the brochure touts that Remicade is "Preferred Over Inflectra . . . Inflectra requires trial and failure on Remicade prior to [Inflectra] utilization."

[23] Jared S. Hopkins, *What's Harder Than Making Copycat Biotech Drugs? Selling Them*, Bloomberg (Aug. 15, 2017).



72. Given the widespread gaps in Inflectra's insurance coverage—caused by J&J—providers using infliximab have overwhelmingly chosen to stock *only* Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by commercial or government insurance plans that *do* cover the product. The effective foreclosure of biosimilars thereby is expanded well beyond the 70 percent of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about *90 percent* of healthcare provider accounts using infliximab had purchased *no Inflectra at all*.

C. J&J Has Further Barred Access Through Exclusionary Contracts with Providers

73. To further amplify Inflectra's foreclosure—even beyond the population of patients covered by insurance plans that have agreed to J&J's exclusivity terms, and the spillover effect on providers discussed above—J&J has imposed exclusionary contracts on providers themselves (e.g., clinics, hospitals, etc.).

74. After Inflectra's introduction, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but *only* if the provider committed to buy Remicade for nearly all of its infliximab needs. To be eligible for rebates, J&J required providers to maintain purchase levels for Remicade at very close to the levels of the year *before* Inflectra's launch—when Remicade was the *only* infliximab option. With about 30 percent of prescriptions in any year representing new patients (and a certain percentage of existing patients exiting therapy each year), this condition also requires providers to use Remicade for new patients if they wish to secure payment from J&J, thus bundling contestable and incontestable demand for Remicade. Like its insurer-level contracts, these contracts as a practical matter make Remicade the exclusive infliximab with the participating providers.

75. J&J has also used multi-product bundling in its provider-level contracts. As one analyst reported, "J&J bundled several drugs and medical devices for larger hospitals, making Inflectra less economical."[24] Conditioning rebates linked to *other* J&J products upon a promise not to do business with Inflectra only exacerbates the exclusionary nature of J&J's contracts.

76. Pfizer was and is prepared to negotiate with providers to make Inflectra the lower-priced infliximab option on a per-unit basis, and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade. But as with insurer contracts, to secure the

[24] Gal, *supra* note 15, at 1.

right to deal freely as to Inflectra (i.e., principally as to new patients), the providers would lose significant J&J rebates on their existing Remicade patient bases.

77. For Pfizer to make up the J&J rebates/discounts that insurers and providers would lose on their existing Remicade patients, Pfizer would have to price Inflectra below its own average variable cost. This is because the lost J&J rebates/discounts are based on the much larger base of existing Remicade patients, whereas Pfizer would be serving a much smaller group of new patients, at least in the near term.

78. When the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost. As a result, biosimilar competition to Remicade is foreclosed.

79. The combined effect of J&J's multifaceted exclusionary scheme has been to foreclose Inflectra from approximately 90 percent of the provider account distribution channel essential to connecting Inflectra with patients of any kind.

J&J HAS MONOPOLY POWER IN THE RELEVANT MARKETS

80. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

81. For years before Inflectra's entry, J&J's ASP for Remicade increased, yet Remicade did not lose business. Between 2007 and 2017, Remicade's ASP increased more than 62 percent. Despite Remicade's price hikes, unit sales of Remicade have actually grown 15 percent during the period from 2012 to 2016.

82. Inflectra's introduction has done nothing to erode Remicade's monopoly power: Since Inflectra was launched, Remicade's ASP has continued to increase without impacting

Remicade's market position. Ten months after Inflectra was introduced, Remicade still accounts for over 96 percent of all infliximab sales. Indeed, J&J has confirmed that "biosimilar competition" has had "very little impact" on Remicade.[25]

83. As noted, infliximab is an infusion-administered TNF-inhibiting immuno-suppressant with FDA approved indications for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease, and plaque psoriasis (together, the "Relevant Indications").

84. The broadest appropriate relevant product market is infusion-administered drugs whose approved labeling from the FDA (a) encompasses one or more of the Relevant Indications, and (b) is without restriction for the applicable Relevant Indication, that is to say, the labeling does not specify that the drug may be used for the applicable Relevant Indication only after the patient has not responded to another therapy (the "Relevant Product Market").[26] Remicade enjoys a share of over 60 percent in the Relevant Product Market, nearly the same share it had before Inflectra entered.

85. The following infusion-administered therapies have been approved as unrestricted therapies for the Relevant Indications:

- ***Rheumatoid Arthritis*:**
    - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
    - Simponi Aria (golimumab) (J&J) (TNF-inhibiting immuno-suppressant)
    - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
    - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)

[25] Johnson & Johnson, Q1 2017 Results Earnings Call Transcript (Apr. 18, 2017), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.

[26] For example, the FDA approved Rituxan for the treatment of moderate to severe active rheumatoid arthritis in adults only after treatment with at least one other TNF antagonist has been used and did not work well enough.

- Orencia IV (abatacept) (Bristol-Myers Squibb) (synthetic recombinant DNA technology immune-suppressant)
- Actemra IV (tocilizumab) (Roche) (interleukin-6 blocker) (IL-6 blocker)

- ***Psoriatic Arthritis*:**
  - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
  - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
  - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
  - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
  - Orencia IV (abatacept) (Bristol-Myers Squibb) (synthetic recombinant DNA technology immuno-suppressant)
- ***Ankylosing Spondylitis*:**
  - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
  - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
  - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
- ***Plaque Psoriasis*:**
  - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
  - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
  - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
  - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
- ***Crohn's Disease*:**
  - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
  - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
  - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
  - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)

- Entyvio (vedolizumab) (Takeda) (integrin receptor antagonist monoclonal antibody)

- ***Ulcerative Colitis*:**
  - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
  - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
  - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
  - Entyvio (vedolizumab) (Takeda) (integrin receptor antagonist monoclonal antibody)

These infusion therapies are referred to collectively as the "Relevant Products."

86. Certain non-infusion drugs are also indicated to treat the Relevant Indications. None of those drugs, however, is a reasonable substitute for the infusion-administered products. None significantly constrains the prices J&J is able to charge for Remicade.

87. The non-infusion products approved for the Relevant Indications include oral medications (e.g., Xeljanz) and self-injectables (e.g., Humira, Enbrel). These products are patient-administered. Infusion drugs, by contrast, must be delivered by healthcare professionals in a clinical setting (e.g., hospitals or infusion centers) during infusion sessions that take upwards of two hours.

88. Physicians are not likely to switch from prescribing their patients infliximab to prescribing those non-infusion products in response to a small but significant non-transitory change in the price of infliximab.

89. Not only are the infusion and non-infusion treatments different kinds of therapies, but they are most often sold to different buyers, on different contracts, and are distributed by different means:

- Infliximab is, as described above, sold primarily to hospitals and clinics and is almost never stocked by retail pharmacies (only rarely being stocked by certain specialty pharmacies). After administering the infusion treatments to their patients, the hospitals and clinics seek reimbursement from the patients' insurers or government payers.
- By contrast, non-infusion drugs such as Xeljanz, Humira, and Enbrel are primarily sold to and distributed in the pharmacy channels. Physicians who prescribe these non-infusion drugs generally do not administer the treatments and do not bear financial risk with respect to the drug selected.
- Non-infusion drugs are also typically covered by insurance through a ***pharmacy*** benefit plan. These are products that insured patients obtain using their "pharmacy" cards. Such drugs are put out for bid periodically by insurers and/or pharmacy benefit managers. The bidding process generally does not even include infusion and other therapies not stocked in a retail pharmacy.
- By contrast, infusion therapies generally are treated as part of the basic ***medical*** coverage provided by health insurers. Infusion therapies are thus generally put out for bid separately from self-administered therapies.

90. Beyond the medical reasons physicians may have for prescribing an infusion therapy as opposed to a non-infusion therapy, patients exhibit strong preferences for one form of therapy over another. Patients with active lifestyles often prefer self-administered treatments. Infusion therapy, on the other hand, is often preferred by patients with needle aversions, or by patients who prefer to have their treatments administered by medical professionals.

91. In addition, infusion and non-infusion therapies are offered at very different price points: On an annual basis, Enbrel and Humira (which are self-administered therapies) at list price are at least twice as expensive as Remicade (which is an infusion therapy) for patients stabilized on them.

92. Because of these various factors, a small but significant non-transitory increase in price of infusion therapies would not have a meaningful impact on the demand for non-infusion therapies, and vice-versa.

93. As noted, the Relevant Product Market includes certain segments that qualify themselves as Relevant Markets, in which J&J also possesses monopoly power. For example:

94. ***Specific-use product markets.*** Specific-use product markets are predicated on infusion-administered therapies for the Relevant Indications. A small but significant non-transitory increase in price for an infusion product in each of these specific-use product markets would not cause substitution to non-infusion medicines approved for the same indication. In each category, Remicade has been the dominant infusion-administered therapy. The categories are as follows:

- ***Infusion-administered therapies for Crohn's disease.*** Remicade accounts for over 70 percent of prescriptions to patients of infusion-based drugs indicated for Crohn's disease.
- ***Infusion-administered therapies for rheumatoid arthritis.*** Remicade accounts for nearly 55 percent of prescriptions to patients of infusion-based drugs indicated for rheumatoid arthritis. When combined with the share of its product Simponi Aria, J&J commands an aggregate of nearly 65 percent of prescriptions to patients in this category.

- ***Infusion-administered therapies for ulcerative colitis.*** Remicade accounts for nearly 70 percent of prescriptions to patients of infusion-based drugs indicated for ulcerative colitis.
- ***Infusion-administered therapies for psoriatic arthritis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs indicated for psoriatic arthritis.
- ***Infusion-administered therapies for ankylosing spondylitis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs indicated for ankylosing spondylitis.
- ***Infusion-administered therapies for plaque psoriasis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs for plaque psoriasis.

95. ***Clinic-based product market.*** The Relevant Product Market encompasses a submarket consisting of sales of the Relevant Products to non-hospital clinics (including free-standing clinics and physician offices with infusion chairs) that administer infusion therapies to patients. Such a submarket is properly treated as a relevant submarket among other reasons because J&J is able to price discriminate between hospitals and non-hospital clinics. The U.S. antitrust enforcement agencies and economists recognize that relevant antitrust product markets can be based on categories of customers against whom sellers can exercise price discrimination, i.e., differential pricing.[27] Non-hospital clinics are subject to successful price discrimination by J&J. J&J can and does identify and target clinics for differential pricing. There are significant differences in the rebates and discounts J&J makes available to non-hospital clinics as compared

[27] *See, e.g.*, U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (2010), § 3.

to hospital customers. Moreover, a small but significant non-transitory increase in the price of Remicade or other Relevant Products will not induce infusion clinics to switch to self-administered therapies. A very substantial percentage of provider accounts that purchase infliximab are non-hospital clinics.

96. ***Product markets for new and existing patients.*** As described above, J&J has a substantial base of existing Remicade patients, the substantial majority of whom are not likely to switch to another therapy, even a biosimilar, if they have achieved relief with Remicade—even in response to a small but significant non-transitory increase in price for Remicade. By contrast, for new patients who are candidates for infusion-administered therapies for the Relevant Indications, Inflectra *is* a reasonable substitute for Remicade. Thus, there is a distinct product market for sales of Relevant Products to new patients in need of infusion-administered therapies for the Relevant Indications. There is also a distinct product market for patients already stabilized on Remicade—a market dominated by Remicade. As described above, J&J's scheme has bundled its control over the latter market (for patients stabilized on Remicade) to thwart competition in the former market (for new patients in need of infusion therapy).

97. ***Infliximab product market.*** After discovery, the data may also support an infliximab-only product market. Among other things, J&J has been able to raise prices for Remicade consistently without losing significant sales to other branded drug products. Both J&J and Pfizer consider Remicade and Inflectra to be particularly close substitutes. For example, J&J's marketing materials focus on comparisons of price and clinical effectiveness between Remicade and infliximab biosimilars, and do not reference any other therapies, and its "Biosimilar Readiness Plan" similarly ignores other therapies, focusing instead on the unique

competitive threat posed by biosimilars. Inflectra's marketing materials likewise focus on Remicade, not on other therapies.

98. ***Barriers to entry.*** Substantial barriers to entry exist to developing other infusion-administered drug therapies for the Relevant Indications generally, and infusion-administered TNF inhibitors specifically. The development of a new therapy requires tens if not hundreds of millions of dollars and substantial risk, as any new product must survive years of research and development, clinical trials, and FDA approval. If left unchecked, J&J's conduct will serve as an additional barrier to entry, as potential new entrants will recognize that they will be unable to break J&J's "rebate trap" and thus to profitably enter the Relevant Markets—and consequently will not invest the resources necessary to develop biosimilars.

99. While a second biosimilar to Remicade has been approved—called Renflexis, sponsored by Merck and Samsung—the sponsoring firms had to overcome just the kind of substantial burdens noted above, and began the effort long before J&J commenced its scheme to exclude biosimilar competition. J&J itself has expressed confidence in maintaining its Remicade dominance despite the potential entry of Renflexis based on its exclusionary contracting strategy. Pfizer has received marketplace feedback that Renflexis will face the same access challenges from J&J's scheme as Inflectra.

100. J&J's scheme—including coercive contracts bundling the incontestable demand (existing patients) with contestable demand (new patients), and promoting the results of its exclusionary insurer-level contracts to create uncertainty about Inflectra among providers—has led directly, with J&J's active encouragement, to nearly all provider accounts that use infliximab declining to purchase Inflectra *at all*. Even if some portion of a provider's patient base may be covered, providers are unwilling to risk using Inflectra only to ultimately be denied coverage. A

single denied claim can cost a provider in excess of $4,000, whereas the typical provider savings in product acquisition cost for a covered Inflectra claim is $200-300. Because Remicade is nearly universally covered, providers have taken the "safe" option and stocked Remicade over Inflectra, thus increasing the already-substantial foreclosure caused by J&J's exclusionary contracts. Thus, as a practical matter, J&J's scheme has foreclosed Inflectra from *approximately 90 percent of provider accounts using infliximab*, the essential channel of distribution for infliximab. And, as noted, in terms of sales, Remicade continues to control over 96 percent of infliximab unit sales.

101. ***Geographic market.*** The relevant geographic market for the Relevant Markets alleged herein is the United States of America and its possessions and territories, as these products are marketed and sold on a national basis.

J&J's CONDUCT HAS STIFLED COMPETITION IN THE RELEVANT MARKETS, THEREBY MAINTAINING AND ENHANCING ITS MONOPOLY POWER AND INJURING PFIZER

102. J&J's scheme has led to the near total foreclosure of Inflectra with patients across the country. First, its exclusionary contracts with health insurers alone—including with most of the largest health insurers in the country—have foreclosed Pfizer's ability to compete for at least 70 percent of patients covered by commercial health insurance plans in the United States. Second, J&J's exclusionary contracts with certain providers have foreclosed Pfizer's ability to compete even for patients covered by plans that do provide reimbursement for Inflectra. And, as discussed, the reimbursement challenges (created by J&J) have led most provider accounts to decline to purchase Inflectra at all, with approximately 90 percent of provider accounts that use infliximab across the country not stocking Inflectra at all. As of September 2017, J&J maintained over 96 percent share of infliximab unit sales in the U.S.

103. Despite vigorous efforts to compete—including offering guarantees that Inflectra would be less expensive unit-for-unit than Remicade—Pfizer has been foreclosed from gaining a competitive foothold as a direct result of J&J's scheme. In the absence of Remicade's exclusionary practices, Inflectra's growth in the Relevant Markets would be substantially greater than it has been, and would be substantially larger in the future. J&J's conduct has deprived Pfizer of (a) past profits; (b) future profits; and (c) the value of invested capital from unrealized efforts to enter and expand in the Relevant Markets. Further, Pfizer's current and prospective customer relationships and goodwill have been, and will continue to be, impaired. J&J's conduct, if allowed to continue, will also dampen the incentives of Pfizer and other biosimilar developers to invest the substantial resources needed to bring biosimilars to the market. Thus, the aims of the BPCIA will have been thwarted.

104. J&J's activities have not only harmed Pfizer, they have caused substantial harm to the competitive process as well as to government payers and to consumers, who have been deprived of the principal benefits of competition—more choices and lower prices. The anticompetitive effects of J&J's conduct are evident in its pricing of Remicade since Inflectra's entry. Despite the fact that Pfizer has offered substantial discounts and a lower ASP to compete for business with insurers and healthcare providers, J&J has been able to *increase* the price of Remicade without losing any significant share or volume of sales to Pfizer (or any other competitor). J&J's prices for Remicade have been increasing by every measure. J&J has increased Remicade list prices twice since FDA approval of Inflectra. These increases alone raised Remicade's list price nearly 9 percent. Remicade's actual ASP (which, as noted above, is net of discounts, rebates, and other price concessions) has also increased since Inflectra's entry—negating any claim that J&J's rebates qualify as meaningful price competition.

105. There is no efficiency or cost-reducing justification for J&J's coercive and exclusionary insurer- or provider-level contract terms. J&J has not achieved improved production costs, or economies of scale or scope through its contracting strategies. J&J also has achieved no improvements in the Remicade treatment through its contracting strategies.

106. If J&J's conduct is not prohibited, it will be adopted by other originator biologics firms aiming to preserve their dominant positions. As the first major biosimilar approval, this case will be a bellwether for the success of Congress's biosimilars initiative, as embodied in the BPCIA.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violation of 15 U.S.C. § 2
Monopolization of All Relevant Markets

107. Pfizer repeats and realleges Paragraphs 1 through 106 as set forth herein.

108. J&J has monopolized the Relevant Markets in violation of Section 2 of the Sherman Act.

109. J&J has monopoly power in the Relevant Markets.

110. Through the scheme described above, and other conduct likely to be revealed in discovery, J&J has willfully and unlawfully maintained and enhanced its monopoly power in violation of Section 2 of the Sherman Act. J&J's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

111. J&J's scheme has stifled competition in the Relevant Markets and thwarted Congress's purpose in enacting the BPCIA.

112. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's

pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Markets.

113. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

114. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

SECOND CLAIM FOR RELIEF
Violation of 15 U.S.C. § 2
Attempted Monopolization of All Relevant Markets

115. Pfizer repeats and realleges Paragraphs 1 through 114 as set forth herein.

116. J&J has attempted to monopolize the Relevant Markets in violation of Section 2 of the Sherman Act.

117. J&J is violating Section 2 of the Sherman Act by attempting to implement the anticompetitive scheme set forth above with the specific intent to monopolize the Relevant Markets. J&J's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

118. There is a dangerous probability that J&J will succeed in monopolizing the Relevant Markets through its anticompetitive scheme.

119. J&J's scheme has stifled competition in the Relevant Markets and thwarted Congress's purpose in enacting the BPCIA.

120. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars,

and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's pricing is not the clearly predominant means by which competition is dangerously likely to be foreclosed in the Relevant Markets.

121. Even if price were deemed to be the clearly predominant means by which competition is dangerously likely to be foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

122. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

THIRD CLAIM FOR RELIEF
Violation of 15 U.S.C. § 14
Sale on Condition to Exclude Inflectra and Other Infliximab Biosimilars or Impose a Fail First Requirement and to Force Use of Remicade in All Relevant Markets

123. Pfizer repeats and realleges Paragraphs 1 through 122 as set forth herein.

124. J&J has entered into agreements with insurers (which reimburse Remicade) and providers (which purchase Remicade), whereby it has conditioned the availability of discounts, rebates, and/or other price concessions on insurers and/or providers eliminating or drastically curtailing their dealings with Inflectra (or any other infliximab biosimilar).

125. J&J's agreements function as exclusive agreements, what are for all practical purposes sole-source agreements, the effect of which is to foreclose substantially competition from rivals, such as Pfizer, in the sale of the infliximab to medical providers, in violation of Section 3 of the Clayton Act.

126. The essence of the J&J-insurer contracts is to pay the insurers to exclude biosimilar alternatives from their prescription drug or medical benefits coverage, whereby the

insurers either deny coverage altogether or restrict coverage to only the rarest of circumstances. The insurers, as the payers for the treatment, have the ability to exclude selected drugs from coverage and as a result, patients and providers do not have a practical ability to choose Inflectra or other infliximab biosimilars over Remicade where coverage is not available. Moreover, because insurers wield power over providers with the ability to grant or withhold coverage for treatment, and because providers are risk-averse when it comes to buying and stocking medications such as infliximab, the providers are effectively compelled to stock Remicade exclusively.

127. The intent and effect of the insurers' performance of these contracts is to cause providers to forgo alternatives and to drive all treatment sales to J&J. The result of the J&J-insurer contracts thus is the amplification of foreclosure, such that Inflectra and other biosimilars are denied access to approximately 90 percent of provider accounts and foreclosed from competition in the Relevant Markets.

128. Because providers and insurers are the gateway for the distribution and sale of the Relevant Products, there are no viable alternative means of distribution or sale and substantial foreclosure exists. Biosimilar competitors to J&J have no practical alternative means of selling infliximab to patients.

129. These de facto exclusive arrangements are in effect durable long-term agreements because the incentives J&J has exploited are not likely to change. So long as J&J's contracts remain in place, biosimilars will not be able to dent J&J's base of existing patients, and the incentives underlying J&J's contracts will remain. No insurer can practically walk away from and not continue to perform under the J&J agreement due to the above-discussed penalties.

130. The effect of each such agreement is and has been to substantially lessen competition in the Relevant Markets. The aggregate impact of such agreements is and has been to substantially lessen competition or tend to create a monopoly in the Relevant Markets.

131. By imposing such conditional contracts, J&J is directly and proximately foreclosing Pfizer and other competitors from a substantial portion of the Relevant Markets.

132. J&J's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 102 through 106.

133. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

FOURTH CLAIM FOR RELIEF
Violation of 15 U.S.C. § 1
Agreements in Restraint of Trade in All Relevant Markets

134. Pfizer repeats and realleges Paragraphs 1 through 133 as set forth herein.

135. J&J has entered into agreements with insurers and providers of Remicade with the purpose and effect of unreasonably restraining trade and commerce in the Relevant Markets.

136. J&J's solicitation and enforcement of the exclusionary contracts described above constitute unlawful agreements, contracts, and concerted activity that unreasonably restrain trade in the Relevant Markets in violation of Section 1 of the Sherman Act.

137. J&J's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 102 through 106.

138. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's

pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Markets.

139. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

140. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

PRAYER FOR RELIEF

141. WHEREFORE, Pfizer respectfully prays that the Court enter judgment against J&J and in favor of Pfizer, as follows:

a. Awarding Pfizer money damages, trebled pursuant to law, in an amount in excess of $150,000.00 (exclusive of interest and costs);

b. Awarding Pfizer the costs of the lawsuit, including its reasonable attorneys' fees and court costs;

c. Declaring J&J's conduct unlawful and in violation of the above-referenced statutes;

d. Entering appropriate preliminary and permanent injunctive relief barring J&J from continuing to undertake its anticompetitive scheme, including its exclusionary contracts; and

e. Ordering such other and further relief as the Court may deem just, proper, and equitable.

JURY TRIAL DEMANDED

142. Pfizer demands a trial by jury for all issues triable by jury.

Dated: September 20, 2017
Philadelphia, PA.

Respectfully submitted,

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